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ART UNIT	PAPER NUMBER
3626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/584,936	KAHN M.D. PH.D ET AL.
	Examiner	Art Unit
	Alexander Kalinowski	3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,31-44 and 110-138* is/are pending in the application.

4a) Of the above claim(s) _ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,31-44 and 110-138* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Recent Statutory Changes to 35 U.S.C. § 102(e)

On November 2, 2002, President Bush signed the 21st Century Department of Justice Appropriations Authorization Act (H.R. 2215) (Pub. L. 107-273, 116 Stat. 1758 (2002)), which further amended 35 U.S.C. § 102(e), as revised by the American Inventors Protection Act of 1999 (AIPA) (Pub. L. 106-113, 113 Stat. 1501 (1999)). The revised provisions in 35 U.S.C. § 102(e) are completely retroactive and effective immediately for all applications being examined or patents being reexamined. Until all of the Office's automated systems are updated to reflect the revised statute, citation to the revised statute in Office actions is provided by this attachment. This attachment also substitutes for any citation of the text of 35 U.S.C. § 102(e), if made, in the attached Office action.

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102 in view of the AIPA and H.R. 2215 that forms the basis for the rejections under this section made in the attached Office action:

> **A person shall be entitled to a patent unless –**
>
> **(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.**

35 U.S.C. § 102(e), as revised by the AIPA and H.R. 2215, applies to all qualifying references, except when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. For such patents, the prior art date is determined under 35 U.S.C. § 102(e) as it existed prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. § 102(e)).

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102 prior to the amendment by the AIPA that forms the basis for the rejections under this section made in the attached Office action:

> **A person shall be entitled to a patent unless –**
>
> **(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.**

For more information on revised 35 U.S.C. § 102(e) visit the USPTO website at www.uspto.gov or call the Office of Patent Legal Administration at (703) 305-1622.

DETAILED ACTION

Claims 1-11, 31-44, and 110-138 are presented for examination.

Specification

The abstract of the disclosure is objected to because the abstract contains more than 150 words. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11, 31-44, and 110-138 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al., "A Methodology for Determining Patients' Eligibility for Clinical Trials" (hereinafter Tu) in view of Clintrial 4.

As per claim 1, Tu discloses one computer readable medium collectively carrying a machine readable database a database including

at least identifying first patient eligibility criteria for a first clinical trial protocol (i.e. basic entry requirements satisfied?)(Fig. 2); and

Tu does not explicitly disclose

a first plurality of workflow tasks for said first clinical trial protocol, said first plurality of workflow tasks including post-enrollment workflow.

However, Clintrial 4 discloses a first plurality of workflow tasks for said first clinical trial protocol, said first plurality of workflow tasks including post-enrollment workflow (i.e. clinical data management system, clintrial admin, etc.)(pages 1-2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include a first plurality of workflow tasks for said first clinical trial protocol, said first plurality of workflow tasks including post-enrollment workflow as disclosed by Clintrial 4 within Tu for the motivation of a product that delivers clean accurate data while ensuring regulatory compliance (see page 1).

As per claim 2, Tu discloses a medium according to claim 1, wherein said database further identifies preliminary patient eligibility criteria applicable to said first clinical trial protocol (i.e. routine tests ok?)(Fig. 2).

As per claim 3, Tu does not explicitly disclose a medium according to claim 1, wherein said database identifies a term by reference to a controlled medical terminology database.

However, Clintrial 4 discloses said database identifies a term by reference to a controlled medical terminology database (i.e. clintrial classify). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include said database identifies a term by reference to a controlled medical terminology database as disclosed by Clintrial 4 within Tu for the motivation of a product that delivers clean accurate data while ensuring regulatory compliance (see page 1).

As per claim 4, Tu does not explicitly discloses a method according to claim 1, wherein said first plurality of workflow tasks includes data management tasks.

However, Clintrial 4 discloses wherein said first plurality of workflow tasks includes data management tasks (i.e. clintrial admin, clintrial enter)(page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include wherein said first plurality of workflow tasks includes data management tasks as disclosed by Clintrial 4 within Tu for the motivation of a product that delivers clean accurate data while ensuring regulatory compliance (see page 1).

As per claim 5, Tu does not explicitly disclose a method according to claim 4, wherein said post-enrollment workflow tasks include post-enrollment patient management tasks.

However, Clintrial 4 discloses wherein said post-enrollment workflow tasks include post-enrollment patient management tasks (i.e. clintrial admin, clintrial enter)(page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include wherein said post-enrollment workflow tasks include post-enrollment patient management tasks as disclosed by Clintrial 4 within Tu for the motivation of a product that delivers clean accurate data while ensuring regulatory compliance (see page 1).

As per claim 6, Tu discloses a method according to claim 4, wherein said data management tasks include an instruction for a clinician to complete a specified form i.e. automated eligibility determination)(pages 2-3).

As per claim 7, Tu discloses a method according to claim 4, wherein said data management tasks include an instruction for a clinician to obtain informed consent of a patient (Fig. 2).

As per claim 8, Tu discloses a method according to claim 7, wherein said first plurality of workflow tasks includes an instruction to obtain specified patient medical information before said instruction to obtain informed consent (i.e. routine test results)(Fig. 2).

As per claim 9, Tu and Clintrial 4 do not explicitly disclose a method according to claim 8, wherein said first plurality of workflow tasks includes a pre-enrollment instruction to obtain specified patient medical information after said instruction to obtain informed consent.

However, the Examiner takes official notice that it was well known in medical informatics arts to obtain patient consent prior to enrollment. The motivation for this feature was to ensure the subject would enroll upon qualification. It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include said first plurality of workflow tasks includes a pre-enrollment instruction to obtain

specified patient medical information after said instruction to obtain informed consent within Tu and Clintrial 4 for the motivation stated above.

As per claim 10, Tu discloses a method according to claim 7, wherein said data management tasks further include an instruction to enroll a patient into a clinical trial.(i.e. enroll)(Fig. 2)

As per claim 11, Tu discloses a method according to claim 1, wherein said data management tasks include an instruction to enroll a patient into a clinical trial (Fig. 2).

As per claim 31, Tu discloses at least one computer readable medium collectively carrying a library each identifying, for a respective clinical trial protocol, at least one member of the group consisting of patient eligibility criteria and protocol workflow tasks (Fig. 2).

Tu does not explicitly disclose
identifying a plurality of machine readable protocol databases.

Clintrial 4 discloses identifying a plurality of machine readable protocol databases (i.e. clintrial design)(page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include identifying a plurality of machine readable protocol databases as disclosed by Clintrial 4 within Tu for the motivation of a product that delivers clean accurate data while ensuring regulatory compliance (see page 1)

As per claim 32, Tu does not explicitly disclose a medium according to claim 31, further comprising means for providing access to individual ones of said protocol databases by each of a plurality of clinical sites in accordance with predetermined site eligibility criteria.

However, Clintrial 4 discloses providing access to individual ones of said protocol databases by each of a plurality of clinical sites in accordance with predetermined site eligibility criteria ((i.e. clintrial admin, clintrial multisite)(page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include providing access to individual ones of said protocol databases by each of a plurality of clinical sites in accordance with predetermined site eligibility criteria as disclosed by Clintrial 4 within Tu for the motivation of a product that delivers clean accurate data while ensuring regulatory compliance (see page 1)

As per claim 33, Tu discloses a medium according to claim 31, wherein different ones of said protocol databases were prepared by different protocol designers (page 1-2).

As per claim 34, Tu discloses a medium according to claim 31, wherein each of said protocol databases identifies:

patient eligibility criteria for the respective clinical trial protocol pages 1-2).

Tu does not explicitly disclose

a plurality of workflow tasks for the respective clinical trial protocol, said plurality of workflow tasks including post-enrollment workflow tasks.

However, Clintrial 4 discloses a plurality of workflow tasks for the respective clinical trial protocol, said plurality of workflow tasks including post-enrollment workflow tasks (i.e. clinical data management system, clintrial admin, etc.)(pages 1-2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include a plurality of workflow tasks for the respective clinical trial protocol, said plurality of workflow tasks including post-enrollment workflow tasks as disclosed by Clintrial 4 within Tu for the motivation of a product that delivers clean accurate data while ensuring regulatory compliance (see page 1).

As per claim 35, Tu discloses a medium according to claim 34, wherein each of said protocol databases further
identifies preliminary patient eligibility criteria applicable to the respective clinical trial protocol (pages 1-2)

As per claim 36, Tu does not explicitly disclose a medium according to claim 31, wherein each of said protocol databases identifies:
a plurality of patient management tasks for the respective clinical trial protocol; and a plurality of data management tasks for the respective clinical trial protocol.

However, Clintrial discloses wherein each of said protocol databases identifies:

a plurality of patient management tasks for the respective clinical trial protocol; and a plurality of data management tasks for the respective clinical trial protocol (i.e. clintrial design, clintrial enter)(page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include wherein each of said protocol databases identifies a plurality of patient management tasks for the respective clinical trial protocol; and a plurality of data management tasks for the respective clinical trial protocol as disclosed by Clintrial 4 within Tu for the motivation of a product that delivers clean accurate data while ensuring regulatory compliance (see page 1).

As per claims 37-39, Tu does not explicitly disclose a medium according to claim 31, wherein at least one of said protocol databases identifies a term by reference to a controlled medical terminology database.

However, Clintrial 4 discloses at least one of said protocol databases identifies a term by reference to a controlled medical terminology database (i.e. clintrial classify)(page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include one of said protocol databases identifies a term by reference to a controlled medical terminology database as disclosed by Clintrial 4 within Tu for the motivation of a product that delivers clean accurate data while ensuring regulatory compliance (see page 1).

As per claim 40, Tu does not explicitly disclose a medium according to claim 31, wherein different ones of said clinical trial protocols address different disease categories

However, Clintrial 4 discloses wherein different ones of said clinical trial protocols address different disease categories (i.e. clintrial design)(page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include wherein different ones of said clinical trial protocols address different disease categories as disclosed by Clintrial 4 within Tu for the motivation of a product that delivers clean accurate data while ensuring regulatory compliance (see page 1).

As per claims 41-44, Tu and Clintrial 4 do not explicitly disclose a medium according to claim 31, wherein each of said machine readable protocol databases includes software objects instantiated from a corresponding predefined set of object classes.

However, the Examiner takes official notice that it was well known in the electronic arts to use object oriented programming. The motivation for object oriented programming is to provide links between heterogeneous computer systems. It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include wherein each of said machine readable protocol databases includes software objects instantiated from a corresponding predefined set of object classes within Tu and Clintrial 4 for the motivation stated above.

As per claim 110, Tu discloses a clinical trials method, comprising the steps of

storing in a library of clinical trial sub-protocol components, a first clinical trial subprotocol component identifying at least one member of the group consisting of a patient eligibility criterion (pages 1-2)

Tu does not explicitly disclose

a protocol workflow task; and

assigning a first sub-protocol component level user access control to said first clinical trial sub-protocol component in said library.

However, Clintrial 4 discloses a protocol workflow task; and

assigning a first sub-protocol component level user access control to said first clinical trial sub-protocol component in said library (i.e. clintrial admin, clintrial design)(page 2).

It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include a protocol workflow task; and assigning a first sub-protocol component level user access control to said first clinical trial sub-protocol component in said library as disclosed by Clintrial 4 within Tu for the motivation of a product that delivers clean accurate data while ensuring regulatory compliance (see page 1).

As per claim 111, Tu does not explicitly disclose a method according to claim 110, comprising the step of storing a plurality of databases each identifying, for a respective clinical trial protocol, at least one member of the group consisting of patient eligibility criteria and protocol workflow tasks,

wherein said step of storing a plurality of databases includes said step of storing a first clinical trial sub-protocol component.

However, Clintrial 4 discloses the step of storing a plurality of databases each identifying, for a respective clinical trial protocol, at least one member of the group consisting of patient eligibility criteria and protocol workflow tasks,
wherein said step of storing a plurality of databases includes said step of storing a first clinical trial sub-protocol component (i.e. clintrial design, clintrial enter)(page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include the step of storing a plurality of databases each identifying, for a respective clinical trial protocol, at least one member of the group consisting of patient eligibility criteria and protocol workflow tasks, wherein said step of storing a plurality of databases includes said step of storing a first clinical trial sub-protocol component as disclosed by Clintrial 4 within Tu for the motivation of a product that delivers clean accurate data while ensuring regulatory compliance (see page 1).

As per claim 112, Tu does not explicitly disclose a method according to claim 111, further comprising the step of providing access to individual ones of said databases by each of a plurality of clinical sites in accordance with predetermined site eligibility criteria.

However, Clintrial 4 discloses providing access to individual ones of said databases by each of a plurality of clinical sites in accordance with predetermined site eligibility criteria (i.e. clintrial multisite)(page 2).). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include providing access to individual ones of said databases by each of a plurality of clinical sites in accordance

with predetermined site eligibility criteria as disclosed by Clintrial 4 within Tu for the motivation of a product that delivers clean accurate data while ensuring regulatory compliance (see page 1).

As per claim 113, Tu does not explicitly disclose a method according to claim 110, wherein said step of assigning a first subprotocol component level user access control to said first clinical trial sub-protocol component in said library comprises the steps of

providing read/write access to said first clinical trial sub-protocol component by a first user; and

providing read but not write access to said first clinical trial sub-protocol component by a second user.

However, Clintrial 4 discloses said step of assigning a first subprotocol component level user access control to said first clinical trial sub-protocol component in said library comprises the steps of

providing read/write access to said first clinical trial sub-protocol component by a first user; and

providing read but not write access to said first clinical trial sub-protocol component by a second user (i.e. clintrial admin)(page 2).). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include said step of assigning a first subprotocol component level user access control to said first clinical trial sub-protocol component in said library comprises the steps of providing read/write

access to said first clinical trial sub-protocol component by a first user; and providing read but not write access to said first clinical trial sub-protocol component by a second user as disclosed by Clintrial 4 within Tu for the motivation of a product that delivers clean accurate data while ensuring regulatory compliance (see page 1).

As per claim 114, Tu discloses a method according to claim 110, wherein said first clinical trial sub-protocol includes first and second sub-protocol sub-components (see Fig. 2).

As per claim 115, Tu does not explicitly disclose a method according to claim 114, further comprising the steps of

assigning a first sub-protocol sub-component level user access control to said first subprotocol sub-component; and

assigning a second sub-protocol sub-component level user access control to said second clinical trials sub-protocol sub-component in said library.

However, Clintrial 4 discloses assigning a first sub-protocol sub-component level user access control to said first subprotocol sub-component; and

assigning a second sub-protocol sub-component level user access control to said second clinical trials sub-protocol sub-component in said library (i.e. clintrial admin)(page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include assigning a first sub-protocol sub-component level user access control to said first subprotocol sub-component; and

assigning a second sub-protocol sub-component level user access control to said second clinical trials sub-protocol sub-component in said library as disclosed by Clintrial 4 within Tu for the motivation of a product that delivers clean accurate data while ensuring regulatory compliance (see page 1).

As per claim 116, Tu discloses a method according to claim 110, further comprising the steps of

storing in said library a second clinical trial sub-protocol component identifying at least one member of the group consisting of a patient eligibility criterion and a protocol workflow task (Fig. 2).

Tu does not explicitly disclose

assigning a second sub-protocol component level user access control to said second clinical trial sub-protocol component in said library.

However, Clintrial 4 discloses assigning a second sub-protocol component level user access control to said second clinical trial sub-protocol component in said library (i.e. clintrial admin)(page 2).). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include assigning a second sub-protocol component level user access control to said second clinical trial sub-protocol component in said library as disclosed by Clintrial 4 within Tu for the motivation of a product that delivers clean accurate data while ensuring regulatory compliance (see page 1).

As per claim 117, Tu discloses a method according to claim 116, wherein said first and second clinical trial subprotocol components are both components of a common clinical trial protocol (Fig. 2).

As per claim 118, Tu does not explicitly disclose a method according to claim 116, wherein said first and second clinical trial subprotocol components are components of different clinical trial protocols.

However, Clintrial 4 discloses said first and second clinical trial subprotocol components are components of different clinical trial protocols (i.e. clintrial design)(page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include said first and second clinical trial subprotocol components are components of different clinical trial protocols as disclosed by Clintrial 4 within Tu for the motivation of a product that delivers clean accurate data while ensuring regulatory compliance (see page 1).

As per claim 119, Tu does not explicitly disclose a method according to claim 116, wherein said step of assigning a first subprotocol component level user access control to said first clinical trial sub-protocol component in said library comprises the step of providing read/write access to said first clinical trial subprotocol component by a first user,

and wherein said step of assigning a second sub-protocol component level user access control to said second clinical trial sub-protocol component in said library comprises the

step of providing read but not write access to said second clinical trial sub-protocol component by said first user.

However, Clintrial 4 discloses said step of assigning a first subprotocol component level user access control to said first clinical trial sub-protocol component in said library comprises the step of providing read/write access to said first clinical trial subprotocol component by a first user, and wherein said step of assigning a second sub-protocol component level user access control to said second clinical trial sub-protocol component in said library comprises the step of providing read but not write access to said second clinical trial sub-protocol component by said first user (i.e. clintrial admin)(page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include said first and second clinical trial subprotocol components are components of different clinical trial protocols as disclosed by Clintrial 4 within Tu for the motivation of a product that delivers clean accurate data while ensuring regulatory compliance (see page 1).

As per claim 120, Tu does not explicitly disclose a clinical trials method, comprising the steps of

storing a plurality of clinical trial sub-protocol components each identifying at least one member of the group consisting of a patient eligibility criterion and a protocol workflow task; and

providing access to individual ones of said clinical trial sub-protocol components by each of a plurality of users in accordance with predetermined sub-protocol component level access controls.

However, Clintrial 4 discloses storing a plurality of clinical trial sub-protocol components each identifying at least one member of the group consisting of a patient eligibility criterion and a protocol workflow task; and

providing access to individual ones of said clinical trial sub-protocol components by each of a plurality of users in accordance with predetermined sub-protocol component level access controls (i.e. clintrial admin, clintrial design, clintrial enter)(page 2).). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include the features listed above as disclosed by Clintrial 4 within Tu for the motivation of a product that delivers clean accurate data while ensuring regulatory compliance (see page 1).

As per claim 121, Tu does not explicitly disclose a method according to claim 120, comprising the step of storing a plurality of databases each identifying, for a respective clinical trial protocol, at least one member of the group consisting of patient eligibility criteria and protocol workflow tasks,

wherein said step of storing a plurality of databases includes said step of storing a plurality of clinical trial sub-protocol components.

However, Clintrial 4 discloses storing a plurality of databases each identifying, for a respective clinical trial protocol, at least one member of the group consisting of patient eligibility criteria and protocol workflow tasks,

wherein said step of storing a plurality of databases includes said step of storing a plurality of clinical trial sub-protocol components (i.e. clintrial admin, clintrial design, clintrial enter)(page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include the features listed above as disclosed by Clintrial 4 within Tu for the motivation of a product that delivers clean accurate data while ensuring regulatory compliance (see page 1).

As per claim 122, Tu does not explicitly disclose a method according to claim 121, further comprising the step of providing access to individual ones of said databases by each of a plurality of clinical sites in accordance with predetermined site eligibility criteria.

However, Clintrial 4 discloses the step of providing access to individual ones of said databases by each of a plurality of clinical sites in accordance with predetermined site eligibility criteria (i.e. clintrial multisite).). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include the features listed above as disclosed by Clintrial 4 within Tu for the motivation of a product that delivers clean accurate data while ensuring regulatory compliance (see page 1).

As per claim 123, Tu does not explicitly disclose a method according to claim 120, wherein said step of providing access to individual ones of said clinical trial sub-protocol components by each of a plurality of users comprises the steps of:

providing read/write access to a first one of said clinical trial sub-protocol components by a first one of said users; and

providing read but not write access to said first clinical trial sub-protocol component by a second one of said users.

However, Clintrial 4 discloses said step of providing access to individual ones of said clinical trial sub-protocol components by each of a plurality of users comprises the steps of: providing read/write access to a first one of said clinical trial sub-protocol components by a first one of said users; and providing read but not write access to said first clinical trial sub-protocol component by a second one of said users (page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include the features listed above as disclosed by Clintrial 4 within Tu for the motivation of a product that delivers clean accurate data while ensuring regulatory compliance (see page 1).

As per claim 124, Tu does not explicitly disclose a method according to claim 123, wherein said step of providing access to individual ones of said clinical trial sub-protocol components by each of a plurality of users further comprises the steps of providing read/write access to a second one of said clinical trial sub-protocol components by said second user.

However, Clintrial 4 discloses said step of providing access to individual ones of said clinical trial sub-protocol components by each of a plurality of users further comprises the steps of providing read/write access to a second one of said clinical trial sub-protocol components by said second user (page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include the features listed above as disclosed by Clintrial 4 within Tu for the motivation of a product that delivers clean accurate data while ensuring regulatory compliance (see page 1).

As per claim 125, Tu discloses a method according to claim 120, wherein a first one of said sub-protocol

components includes first and second sub-protocol sub-components (see Fig. 2).

As per claim 126, Tu does not explicitly disclose a method according to claim 125, further comprising the step of providing access to said clinical trials sub-protocol sub-components by each of a plurality of users in accordance with predetermined sub-protocol sub-component level access controls.

However, Clintrial 4 discloses the step of providing access to said clinical trials sub-protocol sub-components by each of a plurality of users in accordance with predetermined sub-protocol sub-component level access controls (page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include the features listed above as disclosed by Clintrial 4 within Tu for the

motivation of a product that delivers clean accurate data while ensuring regulatory compliance (see page 1).

As per claim 127, Tu does not explicitly disclose a method according to claim 120, further comprising the step of receiving said sub-protocol components from a plurality of different protocol designers.

However, Clintrial 4 discloses the step of receiving said sub-protocol components from a plurality of different protocol designers (page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include the features listed above as disclosed by Clintrial 4 within Tu for the motivation of a product that delivers clean accurate data while ensuring regulatory compliance (see page 1).

With respect to claims 128-138, the claims are similar in scope to claims 31-41 and 110-127 and are rejected on the same basis.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Pat. No. 5,898,586 discloses administering clinical trial material.

"drkoop.com & quintiles" discloses a web site for recruiting clinical trial patients.

"Universal Systems Inc. launches ..." discloses a clinical trial processing solution.

"Versal Technologies ..." discloses a data management system for clinical trials.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander Kalinowski, whose telephone number is (703) 305-2398. The examiner can normally be reached on Monday to Thursday from 9:00 AM to 6:30 PM. In addition, the examiner can be reached on alternate Fridays.

If any attempt to reached the examiner by telephone is unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached on (703) 305-9588. The fax telephone number for this group is (703) 305-7687 (for official communications including After Final communications labeled "Box AF").

Hand delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive, Arlington, VA, 7th Floor, receptionist.

Alexander Kalinowski

Patent Examiner

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